K022201

FEB 0 3 2003

510(K) SUMMARY

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Radius Medical Technologies, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Radius Medical Technologies, Inc. chooses to submit a summary of information respecting safety and effectiveness.

1. Sponsor Name

Submitter's Name:	Radius Medical Technologies, Inc.
Address:	63 Great Road Maynard, MA 01754
Contact Person:	Maureen A. Finlayson
Date of Preparation:	June 28, 2002

2. Device Name

Device Generic Name:	Snare
Device Trade Name:	Radius Micro Snare
Classification Name:	Wire, Guide, Cardiovascular (74DQX)

3. Identification of Predicate or Legally Marketed Device

The Radius Micro Snare is substantially equivalent to the Microvena Amplatz Goose Neck Micro Snare (K970688), the Radius Snare (K021441) and the Radius PTCA Guidewire (K970466).

4. Device Description

The Radius Micro Snare is composed of two primary parts: an outer sheath tube and a core wire with a snare attached to the distal end. The outer sheath acts as a catheter through which the core wire, with snare, slides.

The outer sheath is a stainless steel tube joined to a polyimide tube. The stainless steel and polyimide tubes are covered with PTFE.

The stainless steel core is a solid .008" diameter stainless steel core that is a smaller version of the solid core wire in the FDA cleared Radius PTCA Guidewire

and the FDA cleared Radius Snare. A stainless steel loop is soldered to the distal end of the core. The Radius Micro Snare has loop sizes, which range from 2 - 7 millimeters. The over-all length of the device is 190 centimeters. A molded ABS operating handle is included on the proximal end of the Micro Snare to aid in advancing and retracting the outer sheath over the snare loop.

The Radius Micro Snare will be packaged in a Mylar/Tyvek pouch and ETO sterilized to SAL 10-6.

5. Intended Use

The Radius Micro Snare is intended for use to retrieve and/or manipulate objects in the distal peripheral vessels of the cardiovascular system and hollow viscus. Manipulation procedures include retrieval and/or repositioning of intravascular foreign objects such as coils, balloons, catheters and/or guidewires within the peripheral and cardiovascular system.

6. Comparison of Technological Characteristics

The **Radius Micro Snare** is substantially equivalent in material, design and function to the following predicate devices: the Microvena Amplatz Goose Neck Micro Snare (K970688), the Radius Snare (K021441), and the Radius PTCA Guidewire (K970466).

The Radius Micro Snare is similar in materials, function and design to predicate Radius PTCA Guidewire (K970466) and Radius Snare (K021441). The Radius Micro Snare uses the Radius PTCA Guidewire as its base and adds a snare onto the distal tip of the core guidewire.

The design and function of the Radius Micro Snare is the same as the Microvena Amplatz Goose Neck Micro Snare (K970668). Both are delivered via a cathether/outer sheath tube and both have a snare at the distal end. The intended use of both devices is the same: to retrieve and/or manipulate objects in the distal peripheral vessels of the cardiovascular system and hollow viscus.

7. Performance Testing

The following in vitro performance tests were performed on the Radius Micro Snare:

Tensile Strength
Torque Strength
Tip Flexibility
Biocompatability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 3 2003

Ms. Maureen A. Finlayson
President
Radius Medical Technologies, Inc.
63 Great Road
Maynard, MA 01754

Re: K022201
Trade/Device Name: Radius Micro Snare
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter.
Regulatory Class: Class II
Product Code: MMX
Dated: October 14, 2002
Received: November 6, 2002

Dear Ms. Finlayson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4586. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022201

Device Name: Radius Micro Snare

Indications For Use:

The Radius Micro Snare is intended for use to retrieve and/or manipulate objects in the distal peripheral vessels of the cardiovascular system and hollow viscus. Manipulation procedures include retrieval and/or repositioning of intravascular foreign objects such as coils, balloons, catheters and/or guidewires within the peripheral and cardiovascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022201